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SECTION 6 - SUMMARY OF SAFETY AND EFFECTIVENESS

MALI-TECH LTD. 510(K) Premarket Notification
for the GoldFinger Automatic Blood Lancet Device

510(k) Number K001162

1. **Submitter:**

Mali-Tech Ltd.
P.O.B. 21411
Tel Aviv, 61213 ISRAEL

2. **Date:**

March 30, 2000

3. **Trade Name:**

GoldFinger device (models 1 and 2)

4. **Classification Name:**

Manual, Surgical Instrument for General Use, Blood Lancet - Models 1 and 2 (with a Glucose Test System – Model 2)

5. **Classification:**

The GoldFinger Automatic Blood Lancet device (Model 1), including a cooling system belongs to the CFR classification section 878.4800 and product code 74FMK, (and CFR classification section 862.1345 – for Model 2).

6. **Predicate Device:**

The GoldFinger device is substantially equivalent to a combination of the Easy-Ject device (also manufactured by Mali-Tech Ltd. and the subject of 510(k) document no. K972383) and to the B-D Autolancet device and Microfine + disposable lancets (manufactured by Becton Dickenson & Co., and the subject of 510(k) document no. K822209).

7. **Indications for Use:**
Model 1: The GoldFinger device is an automatic blood lancet device with a cooling mechanism, used to obtain a capillary blood sample.
Model 2: The GoldFinger device is an automatic blood lancet device with a cooling mechanism and Glucometer, used to obtain a capillary blood sample, and for quantitative measurement and display of capillary blood glucose levels.

8. Device Description:

The GoldFinger device is an automatic blood lancet device, with a cooling system. The GoldFinger device is used to obtain a drop of capillary blood for self- blood glucose testing.

The GoldFinger device consists of two major components; the automatic blood lancet device component and the device housing containing the cooling mechanism.

The automatic blood lancet component of the GoldFinger device is a standard mechanical, spring-loaded mechanism used to lance a finger for the purpose of obtaining a capillary blood sample. The spring-loaded mechanism is housed inside a plastic casing. The device contains a cover, which may be opened in order to load a new, sterile lancet into the lancet holder and a release button, which releases the lancet needle in order to perform the needle prick. The lancet is released to a predetermined depth below the skin surface. The automatic blood lancet device component is positioned inside the GoldFinger device housing.

The GoldFinger device housing, contains the cooling mechanism and the automatic blood lancet device carrier. The cooling mechanism consists of a cooling assembly and a cooling disk located at the tip of the device (where the lancet needle is released). The purpose of the metal cooling disk is to cool the area of the skin prior to and during the needle stick, in order to alleviate pain. The tip of the device also contains the depth adjustment dial for setting the appropriate needle depth penetration. There are five different depths of needle penetration available. The lancet needle depth is determined according to the user's skin texture (callused, soft, etc.)

The model 2 GoldFinger device is exactly the same as the model 1 device described above, although the device housing is slightly modified to incorporate a glucometer device. The GoldFinger device housing will be designed to house the Glucometer device component, with appropriate openings for device (glucose strip) access and digital screen (LCD) showing of the glucose level results.

9. Substantial Equivalence:

Based on the intended use and technological characteristics of the predicate devices, the GoldFinger device is substantially equivalent to the predicate devices cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 9 2000

Mali-Tech Ltd.
c/o Ms. Ahava Stein
A. Stein - Regulatory Affairs Consulting
P.O.B. 454
Ginot Shomron 44853
ISRAEL

Re: K001162
Trade Name: GoldFinger Automatic Blood Lancet Models 1 and 2
Regulatory Class: II
Product Code: FMK
Dated: July 20, 2000
Received: August 7, 2000

Dear Ms. Stein:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Bochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K001162

Device Name: GoldFinger Automatic Blood Lancet device

Indications for use: Model 1: The GoldFinger device is an automatic blood lancet device with a cooling mechanism, used to obtain a ~~capillary blood~~ sample.
Model 2: The GoldFinger device is an ~~automatic blood lancet~~ device with a cooling mechanism and Glucometer, used to obtain a capillary blood sample, and for quantitative measurement and display of capillary blood glucose levels.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diane R Vochmer
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001162

Prescription Use X OR Over-The-Counter Use ____
(Per 21 C.F.R. 801.109) (Optional Format 1-2-96)